

REMARKS

1. The Applicants have studied the outstanding Office Action dated July 29, 2009. The present amendment is intended to be fully responsive to all points of rejection raised by the Examiner, and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application are respectfully requested.
2. Claims 1-3, 5, 6, 9-12, 14-16, 18-23 and 26-31 stand rejected. Claims 4, 7, 8, 17, 24 and 25 are objected to as being dependent on a rejected base claim. Claims 2-3, 5, 10 and 13 are deleted herewith, without prejudice. Claims 1, 4, 6, 12, 17, 20, 22, 24-25, 27 and 31 are amended herewith. Claims 32-35 are withdrawn, and a rejoinder thereof is respectfully requested. Claims 1, 4, 6-9 and 11, 12, and 14-31 are pending in the applications and are under consideration.
3. The applicants gratefully acknowledge the Examiner's indication that claims 4, 7, 8, 17, 24 and 25 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Since the applicants have amended the base claims in a manner which they believe renders them allowable, they respectfully request delaying such rewriting until after examination of the amended claim set.
4. Claim 1 has been amended primarily by the incorporation of the subject matter of claim 3 into claim 1. Claim 1 has been further limited by the additional recitation that the implant device "is adapted to remain implanted in its entirety in the patient's body". Support for this additional limitation is to be found in the specification as filed on page 15, paragraph 117, where it is stated that "The introduction device 18 may then be altogether removed, or **remain in position, allowing the bone or other surrounding tissue to grow over it**" (emphasis added). The other claim amendments made in the application are directed merely at correcting the dependencies of claims where the parent claim has been cancelled, or at improving linguistic clarity in claims, or at correcting spelling errors. The applicants submit that no new subject matter has been introduced into the claims.

5. Before submitting arguments relating to the Examiner's specific objections and rejections, the applicants wish to provide an outline explanation of a fundamental difference between the currently claimed invention, and the prior art cited by the Examiner.
6. The device claimed in the present application comprises three elements - a conduit, an expandable structure delivered through the conduit, and a wrapping element for constraining the expandable structure. It is to be emphasized that in the currently claimed invention, **the conduit is an integral part of the device**, and remains implanted within the patient's tissues even after the expandable structure has been completely deployed. This is an important feature which distinguishes the currently claimed invention from prior art devices, where the conduits used do not remain implanted within the subject's body, but are withdrawn after use in inserting any structural elements. This aspect of the present claimed invention has a number of advantages over prior art implants, some of which are delineated in the application. Since the conduit can be inserted through cortical bone, such as a pedicle of a vertebra, it maintains its position and hence the stability of the expandable structure, without the need for bone cement, as used in some of the prior art. Furthermore, the presence of the implanted conduit assists in anchoring the wrapping element in position, and hence assists in maintaining the stability of the expandable structure.

Claim rejections – 35 USC §102

7. Claims 1, 2, 5, 9-12, 14, 29 and 30 stand rejected under 35 U.S.C. 102(e) as being anticipated by Bhatnagar et al. (Pub. No. US 2005/0080425). The Examiner asserts that Bhatnagar et al. discloses variously all of the elements of these claims, including a conduit 44 (figure 8A), through which the device is introduced into the patient's body.
8. The applicants have amended claim 1 to recite that the "implant device is adapted to remain implanted in its entirety in the patient's body". The Applicants submit that the

conduit 44 described in Bhatnagar, is used only as a delivery tube in order to insert the device, and once the retraction procedure is completed, it is removed, even in the case described by Bhatnagar in paragraph [0049] where the spreading assembly may be left within the bone. The conduit cannot therefore be described as being an element of an "implant device (is) adapted to remain implanted in its entirety in the patient's body" as recited in amended claim 1 of the present application. Applicants failed to find in Bhatnagar et al. any teaching or suggestion for an implant device comprising all of the elements recited in amended claim 1 of the present application.

9. The applicants therefore assert that amended claim 1 is patentable over Bhatnagar, and request withdrawal of the rejection thereof under 35 USC 102(e). As all the claims which depends on claim 1 incorporate all its limitations and recite further patentable subject matter, all claims dependent on claim 1 are also deemed patentable.

10. Claims 1, 2, 5, 6, 23, 26-28 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (U.S.5,755,797). The Examiner asserts that Baumgartner discloses variously all of the elements of these claims, including a conduit 6 (figure 3), through which the device is introduced into the patient's body.
11. The applicants have amended claim 1 to recite that the "implant device is adapted to remain implanted in its entirety in the patient's body". The Applicants submit that the conduit 6 described in Baumgartner, is used only as a delivery tube in order to insert the device, and once the support procedure is completed, it is removed, as described in Baumgartner in col. 4, lines 9-10 "When the cavity is completely full, the tube 6 is withdrawn in a known manner from the annular region 4," The conduit cannot therefore be described as being an element of an "implant device (is) adapted to remain implanted in its entirety in the patient's body" as recited in amended claim 1 of the present application. Applicants failed to find in Baumgartner any teaching or suggestion for an implant device comprising all of the elements as recited in amended claim 1 of the present application.

12. The applicants therefore assert that amended claim 1 is patentable over Baumgartner, and request withdrawal of the rejection thereof under 35 USC 102(b). As all the claims which depends on claim 1 incorporate all its limitations and recite further patentable subject matter, all claims dependent on claim 1 are also deemed patentable.

13. Claims 1 and 3 stand rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al. (Pub. No. US 2002/0183761). The Examiner asserts that Johnson et al. discloses variously all of the elements of these claims, including "an introduction member (50) 40 (figure 29) the introduction member 40 comprising a substantially linear conduit (figure 29) having a proximal end through which the device is inserted".
14. The applicants have amended claim 1 to recite that the "implant device is adapted to remain implanted in its entirety in the patient's body". The Applicants submit that the conduit described in Johnson et al, is used only as a delivery tube in order to insert the device, and once the distraction procedure is completed, it is removed, as described in paragraph [0035] "After the wafer(s) have been inserted, the insertion device is removed" The conduit cannot therefore be described as being an element of an "implant device (is) adapted to remain implanted in its entirety in the patient's body" as recited in amended claim 1 of the present application. Applicants failed to find in Johnson et al. any teaching or suggestion for an implant device comprising all of the elements as recited in amended claim 1 of the present application.
15. The applicants therefore assert that amended claim 1 is patentable over Johnson et al., and request withdrawal of the rejection thereof under 35 USC 102(e). Claim 3 is dependent on claim 1 and recites further patentable subject matter. Therefore, claim 3 is also deemed patentable.

Claim rejections – 35 USC §103

16. Claims 1, 15, 16, 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner (US 5,171,280) in view of Bhatnagar et al. (Pub. No. US 2005/0080425). The Examiner asserts that Baumgartner discloses variously all of the elements of these claims, with the exception of the wrapping element. Bhatnagar et al teaches a wrapping element 84 (figure 9) for the purpose of protecting the surrounding tissue from the working mechanism of the spreading assembly (paragraph 0058), and that it would have been obvious to one skilled in the art at the time of the invention to modify the distractor disclosed by Baumgartner to include a wrapping element for the purpose of protecting the surrounding tissue from the working mechanism of the spreading assembly, as taught by Bhatnagar (paragraph 0058).
17. The applicants respectfully submit that, contrary to the Offices assertion, Baumgartner (US 5,171,280) does not show the conduit as recited in amended claim 1. The tube 27 shown in Baumgartner (US 5,171,280) is not part of the implant device, and is intended for deployment of the implant device and for removal once the device has been implanted, as stated in col. 4, lines 51-52 of Baumgartner: "Subsequently, the tube 27 is also removed from the body." The applicants therefore submit that combination of what is shown in Baumgartner (US 5,171,280) with the wrapping element taught by Bhatnagar would not render amended claim 1 of the present application as obvious, and the applicants respectfully request withdrawal of this rejection. As all the claims which depends on claim 1 incorporate all its limitations and recite further patentable subject matter, all claims dependent on claim 1 are also deemed patentable.

Conclusion

18. The applicants therefore respectfully submit that, in the light of the above remarks, all of the pending claims, as variously amended, are novel and unobvious over the cited prior art, recite patentable subject matter, and are therefore allowable. Reconsideration and withdrawal of all rejections and objections, and prompt allowance of this application are therefore earnestly requested.
19. Should the Examiner find any deficiencies in this response, or that a conversation with the agent for the applicants would otherwise facilitate the proceedings regarding the present application, the Examiner is kindly requested to contact Shalom Wertsberger at (401) 289 2891.

Respectfully submitted

/Shalom Wertsberger/

Shalom Wertsberger

Reg. Num 43,359

1 Mathewson Road

Barrington, RI 02806

Phone: (401)289-2891

Fax: (401)289-2892

e-mail:shalom@saltamar.com

Agent for Applicant